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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,606	05/05/2005	Maria Cristina Geroni	17703 (PC27210A)	4724
7590	06/10/2009	EXAMINER		
Peter I Bernstein Scully Scott, Murphy & Presser 400 Garden City Plaza Suite 300 Garden City, NY 11530		WEBB, WALTER E		
		ART UNIT	PAPER NUMBER	
		1612		
		MAIL DATE		DELIVERY MODE
		06/10/2009		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/500,606	GERONI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 2/11/2009.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-9,11,13-15 and 24-30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3,5-9,11,13-15 and 24-30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/10/2009 has been entered.

Applicants' arguments, filed 2/12/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections are newly applied. They constitute the complete set presently being applied to the instant application. The previous rejection has been rendered moot by applicant's amendment.

### ***Claim Rejections - 35 USC § 103***

Claims 1-3, 5-9, 11, 13-15 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzi et al. (WO 98/04524, published February 5, 1998) in view of Cortes et al. (Investigational New Drugs 2000).

Cozzi teaches the acryloyl distamycin derivative of formula I (see page 3 lines 25-30 and page 4 lines 1-5; see also examples that follow pp. 4-7; see also specification

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at pg. 7, lines 12-16). The compounds are taught to be in association with one or more pharmaceutically acceptable carrier and/or diluent (see col. 18, lines 25-28). Cozzi also discloses that the acryloyl distamycin derivatives can be combined with an additional antitumor agent for treating cancer or for ameliorating the conditions of mammals, including humans, suffering from cancer (see page 20 lines 6-13 and lines 20-29). Combined preparations may be simultaneous, separate or sequential, and are administered "in amounts sufficient to produce a therapeutically useful effect" (see pg. 20, lines 10-13). The reference teaches that the compounds of formula I are useful in treating leukemias (**claim 28**) (see pg. 16, lines 9-12).

Cozzi does not teach a protein kinase inhibitor.

Cortes et al. teach that CGP 57148 (STI 571) is a novel agent that inhibits the tyrosine kinase activity of ABL, and that clinical results suggest a very potent anti-leukemia activity with minimal toxicity in patients with Interferon-resistant Ph-positive CML (see pg. 72, left column, 2<sup>nd</sup> paragraph (II Targeted Therapy)).

Generally, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. See MPEP 2144.06. Thus, combining the acryloyl distamycin compounds of Cozzi with the STI 571 of Cortes as claimed in the instant invention would have been *prima facie* obvious since they are both taught to be useful for treating leukemia.

In regard to the "synergistic antineoplastic effect", applicant has defined the term as follows: "inhibition of the growth of tumor, preferably the regression of the tumor, by administering an effective amount of the combination comprising an acryloyl distamycin derivative of formula (I) and a PK inhibitor to mammals, including humans." (See pg. 8, lines 1-4 of the instant specification.) The artisan would reasonably expect inhibition of the growth of leukemia or regression of leukemia from the administration of the acryloyl distamycin compounds of Cozzi and the STI 571 of Cortes, since they both are useful for treating leukemia.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612